IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

On Appeal to the Board of
Appeals and Interferences

Appellant(s) : Jill Tolle et al.   Examiner: Frenel, Vanel.

Serial No.   : 09/941,496   Group Art Unit: 3627

Filed   : August 29, 2001

Title   : SYSTEM AND METHODS FOR GENERATING PHYSICIANS
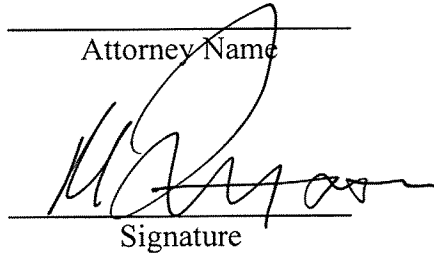   PROFILES CONCERNING PRESCRIPTION THERAPY PRACTICES

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Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On April 18, 2007, Appellants filed a Notice of Appeal from the more than twice

rejection of claims 1-35 contained in the Office Action dated on October 18, 2006 and

maintained in an Advisory Action dated March 21, 2007. The Notice of Appeal was received by

the U.S. Patent and Trademark Office on April 18, 2007. Applicants hereby timely submit,

pursuant to 37 C.F.R. § 41.37, an Appeal Brief in support of the appeal of the rejection of

pending claims 1-35.

I.   <u>REAL PARTY IN INTEREST</u>

The real party in interest is IMS Health Incorporated, 660 West Germantown Pike, Plymouth Meeting, Pennsylvania 19462 ("IMS Health"). IMS Health is the assignee of the entire right, title, and interest in the present application by way of an Assignment executed on December 11, 2001 and January 4, 2002, which Assignment was recorded in the U.S. Patent and Trademark Office on January 15, 2002, at Reel 012491, Frame 0616.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-35 are pending.

In an Office Action dated March 2, 2006, claims 1-35, which are directed to processing methods and systems specifically for 'de-identified' patient records, were rejected under 35 U.S.C. § 103(a) allegedly as being obvious from Portwood et al. U.S. Patent No. 6,305,377 ("Portwood") in view of Edelson et al. U.S. patent No. 5,737,539 ("Edelson").

In a Final Office Action dated October 18, 2006, the obviousness rejection of claims 1-35 was sustained.

An Advisory Action dated March 21, 2007, indicates that Appellants' arguments [presented in previous Replies to Office Actions] were found to be unpersuasive.

IV. STATUS OF AMENDMENTS

No requested amendments are outstanding or awaiting entry.

V.   SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention is directed toward generating a profile from "de-identified" patient records, which profile concerns the prescription therapy practices of physicians in a therapeutic area of interest.

Appellants, in particular, note that their invention is designed toward providing health care industry solutions in the contemporaneous legal, regulatory and social environment in which preserving patient privacy is very importance. For example, under current HIPAA regulations, patient records transmitted between parties cannot include patient identifying information (e.g., patient name, social security numbers or addresses). Only "de-identified" patient records may be exchanged, shared or communicated between parties such as hospitals, pharmacies, insurers, and commercial or non- commercial researchers. Constructing longitudinally linked databases from patient records that do not contain patient identifying information is a data processing challenge, which has been overcome by assignee as described, for example, in co-pending U.S. Patent application filings by Mark Kohan et al. In the instant specification, "whenever a 'patient' or 'patient data' is described . . . it is understood that the patient's identity and personal information are excluded (i.e., the patient is 'de-identified') in order to maintain confidentiality of patient records".

Method claims 1 and 10, and system claim 25 specifically relate to the processing of 'de-identified' patient records. Claims 1 and 10, for example, both recite "receiving . . . de-identified patient prescription records". Claim 25, for example, recites "a mass storage device for storing . . . de-identified patient prescription records."

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Claim 1 reads:

A method for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest, [*See Specification page 4, ¶[0011], paragraph lines 1-],;.* comprising the steps of:

(a)   receiving a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including de-identified patient identification number, dosage, and prescription product information [*See Specification, page 7 ¶[0027] paragraph lines 1-13, page 9 ¶[0031] paragraph lines 6-7, FIG. 2 step 102*];

(b)   receiving user-specified information defining a subset of the historical de-identified patient prescription records [*See Specification page 9 ¶[0031] paragraph lines 8-9, FIG. 2 step 104, page 10 ¶ [0033] paragraph lines 4-8, etc.*];.

(c)   extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset [*See Specification page 10 ¶ [0033] paragraph lines 1-4, FIG. 3 step 120, etc.*];.

(d)   for each de-identified patient, comparing dosage and prescription product information contained in a first extracted historical de-identified patient record with dosage and prescription product information contained in a second extracted historical de-identified patient record [*See Specification page 12 ¶ [0037] paragraph lines 1-12, page 12-13 ¶[0039] paragraph lines 1-17], FIG. 3 step 132, etc.*]; and

(e)   for each comparison made in step (d), categorizing a prescription based on a change in dosage or prescription product [*See Specification ¶ [0037] paragraph lines 1-12, FIG. 3 step 138, 142, and 146, etc.*];

Claim 10 reads:

A method for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest comprising the steps of:

(a)   receiving a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including de-identified patient identification number, prescription product information, date dispensed, dosage, number of days supplied, and refill information [*See Specification, page 7 ¶[0027] paragraph lines 1-13, page 9 ¶[0031] paragraph lines 6-7, FIG. 2 step 102*];

(b)   receiving user-specified information defining a subset of the historical de-identified patient prescription records [*See Specification page 9 ¶[0031] paragraph lines 8-9, FIG. 2 step 104, page 10 ¶ [0033] paragraph lines 4-8, etc.*];.

(c)   extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset[*See Specification page 10 ¶ [0033] paragraph lines 1-4, FIG. 3 step 120, etc.*];

(d)   for each de-identified patient, comparing dosage and prescription product information contained in a first extracted historical de-identified patient record with dosage and prescription product information contained in a second extracted historical de-identified patient

record [*See Specification page 12 ¶ [0037] paragraph lines 1-12, page 12-13 ¶[0039] paragraph lines 1-17], FIG. 3 step 132, etc.*];

(e)   for each comparison made in step (d), categorizing a prescription based on a change in dosage or prescription product [*See Specification ¶ [0037] paragraph lines 1-12, FIG. 3 step 138, 142, and 146, etc.*];

(f)   extracting at least one relevant historical de-identified patient prescription record from the prescriptions categorized at step (e) based on the refill information [*See Specification page 14 ¶ [0041] paragraph lines 1-14 page 16 paragraph lines 1-15, FIG. 6 step 170-172. etc.*];

(g)   for each de-identified patient, determining a refill due date based on the dosage and the number of days supplied for a first prescription [*See Specification page 16 paragraph [0044] lines 5-10, FIG, 6 step 170-172. etc.*];

(h)   for each de-identified patient, comparing the refill due date of the first prescription with the date dispensed for a second prescription [*See Specification page 16 paragraph [0044] lines 5-10, etc.*]; and

(i)   for each comparison made in step (h), categorizing the de-identified patient based on the duration between the refill due date of the first prescription and the date dispensed for the second prescription [*See Specification page 16 paragraph [0044] 1-11, pages 17-18 ¶ [0046] paragraph lines 1-9, FIGS. 7 and 8, etc.*];

Claim 25 reads

A system for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest, comprising:

(a)   a mass storage device for storing a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including a de-identified patient identification number, dosage, number of days supplied and prescription product information, dosage, fill date, and number of days supplied [*See Specification, FIG. 1*]; ;

(b)   an input device, coupled to the mass storage device, for receiving user-specified information which defines a subset of the plurality of historical de-identified patient prescription records [*See Specification, FIG. 1*];;

(c)   a prescription categorizer, coupled to the input device, configured to compare the dosage and the prescription product information contained in a first historical de-identified patient prescription record with the dosage and prescription product information contained in a second historical de-identified patient prescription record, and to categorize a prescription based on a change in dosage or prescription product [*See Specification, page 8 ¶[0029] paragraph lines 1-8, FIG. 1 etc.*]; and

(d)   a persistence calculator, coupled to the prescription categorizer, configured to determine the due date of a first prescription based on the dosage and the number of days supplied, to compare the due date of the first prescription with the fill date of a second prescription, and to categorize the de-identified patient based on the duration between the due

date of the first prescription and the fill date of the second prescription [*See Specification, page 8 ¶[0030] paragraph lines 1-5, FIG. 1 etc.*];.

VI.   GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejection of claims 1-35 under 35 U.S.C. § 103(a) allegedly as being obvious from Portwood et al. U.S. Patent No. 6,305,377 ("Portwood") in view of Edelson et al. U.S. patent No. 5,737,539 ("Edelson").

VII. ARGUMENT

The Examiner's has improperly rejected claims 1-35 under 35 U.S.C. § 103(a) allegedly as being obvious from Portwood in view of Edelson. The Examiner's rejections are incorrect and should be reversed.

35 U.S.C. § 103(a) obviousness rejection

The Examiner has improperly rejected claims 1-3 under 35 U.S.C. § 103(a) by failing to make out a prima facie case of obviousness. (See Office Actions dated October 18, 2006 and March 2, 2007).

To establish a prima facie case of obviousness under §103(a), according to MPEP § 2143, three basic criteria must be met: (a) some suggestion or motivation to modify Portwood in view of Edelson; (b) a reasonable expectation of success; and (c) a teaching or suggestion of all the elements of claims 1-35.

According to MPEP § 2124 "[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. 'To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.' Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)."

The §103(a) rejection of claims 1-35 in the Office Actions does not address or satisfy any of the three criteria required to establish a prima facie case of obviousness.

Careful reading indicates that Portwood and Edleson do not have any disclosure (explicit or inherent), which <u>shows, teaches, suggests, or provides motivation</u> leading to applicants' inventive processing of "de identified patient" records (e.g., longitudinal prescription data from retail pharmacies See specification ¶ [.

Unlike appellants' claimed process, Portwood and Edelson both relate to data processing environments in which patient records are or were not de-identified. For example, Edelson FIGS. 1 and 2 explicitly show patient name, social security number information. Close reading of Edelson shows no awareness or suggestion by either Edelson o Portwood of "de-identified" patient records." Edelson's prescription management system explicitly relies on records having "patient identifiers." (See e.g. Edelson, col. 4 lines 30-35). Similarly, Portwood patient prescription compliance system explicitly relies on "patient data [that] include[s] the patient's name, social security number, and address' (See Portwood col. 8, lines 54 -65, col. 9 lines 6-19, etc.).

Thus, Portwood and Edelson, viewed individually or in combination, do not <u>show, teach, or suggest</u> the elements of claims 1, 10, and 25 that specifically relate to the processing of "de-identified" patient records.

For at least this reason, the Office Actions fail to make a prima facie case of obviousness.

Appellants note that Final Office Action dated October 18, 2006 states that the Examiner relies "upon the clear and unmistakable teaching of Portwood Col. 1 lines 34-67 to col. 2 lines 14) which correspond to Applicant's claimed feature". (See Final Office Action page 3 section (B)). However, careful reading of all of Portwood including the cited portion — col. 1 lines 34-67 to col. 2 lines 14, shows no support for Examiner's position. Unless the citation in

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the Office Action is in error, applicants believe that the Examiner's cited text at col. 1 lines 34-

col. 2 line 14 is as follows:

> In attempts to overcome one or more of these causes, various equipment and systems have been devised. Examples of such systems can be seen in U.S. Pat. No. 4,695,954 which combines a special drug dispenser to be used by a patient in conjunction with a system which monitors the usage of the drugs by the patient. Another system is disclosed in U.S. Pat. No. 4,766,542 wherein patients are automatically contacted by automatic telephone dialing and voice synthesizing equipment to remind them that their prescriptions need to be refilled. U.S. Pat. No. 5,390,238 discloses a system linking the physician, pharmacists, patient, and care provider for the purpose of monitoring medication usage and patient wellness. However, the various prior art systems have proven to be workable only in controlled environments. Even then they leave unsolved many of the numerous other causes of noncompliance.
>
> A second problem relating to medical regimens is lack of easy checking procedures to determine if a prescription complies with a recommended regimen. Currently, the U.S. FDA publishes a Generic Product Identifier (GPI) which is a listing of available drugs coded by their generic chemical composition and a National Drug Code (NDC) which is a listing of available drugs coded by their trade names. However, neither the GPI nor the NDC contain drug reaction information. There does exist a collection of studies which describe known reactions for certain drugs. This collection of studies is referred to herein as the Knowledge Base Drug Code (KDC). In addition, there are other studies which have established classes based on composition of the components which make up a drug. However, a compilation of this available information has not been assembled for easy use.

Appellants have submitted in their previous Reply that the Examiner makes an

error in concluding that the cited portion of Portwood is related "de-identified patent record

processing," or to any of applicants' claimed features related to "de-identified patent record

processing".

Further, with the Examiner's stated position in the Final Office Action that

"applicant does not point to any specific distinction(s) between the features disclosed in the

references and the features that are presently claimed," Appellants note that the Reply dated

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February 20, 2007 at pages 12-15 specifically highlights in italics the claim elements that are distinct from the combined teachings of Portwood and Edleson.

Appellants further submit that these claimed features are not only not shown by Portwood and Edleson they are also not suggested by the combined teachings of Portwood and Edleson.

For example, with respect to claim 1, Portwood and Edelson in combination do not suggest to a person of ordinary skill in the art:

(a)   *receiving a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient* by at least one physician, *each record including de-identified patient identification number*, dosage, and prescription product information;

(b)   *receiving user-specified information defining a subset of the historical de-identified patient prescription records*;

(c)   *extracting at least one relevant historical de-identified patient prescription* record from the received historical de-identified patient prescription records based on the subset;

(d)   *for each de-identified patient, comparing dosage and prescription product* information contained *in a first extracted historical de-identified patient record* with dosage and prescription product information contained in *a second extracted historical de-identified patient record*; and

(e)   *for each comparison made in step (d), categorizing a prescription based on a change in dosage or prescription product.*

For example, with respect to claim 10, Portwood and Edelson in combination do not suggest to a person of ordinary skill in the art:

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:

(a)   *receiving a plurality of historical de-identified patient prescription records* corresponding to prescriptions issued *to at least one de-identified patient* by at least one physician, *each record including de-identified patient identification number*, prescription product information, date dispensed, dosage, number of days supplied, and refill information;

(b)   *receiving user-specified information defining a subset of the historical de-identified patient prescription records*;

(c)   *extracting at least one relevant historical de-identified patient prescription record* from the received historical de-identified patient prescription records based on the subset;

(d)   *for each de-identified patient, comparing* dosage and prescription product information contained in *a first extracted historical de-identified patient record with* dosage and prescription product information contained in *a second extracted historical de-identified patient record;*

(e)   *for each comparison made in step (d), categorizing a prescription based on a change in dosage or prescription product*;

(f)   *extracting at least one relevant historical de-identified patient prescription record* from the prescriptions categorized at step (e) based on the refill information;

(g)   *for each de-identified patient, determining* a refill due date based on the dosage and the number of days supplied for a first prescription;

(h)   *for each de-identified patient, comparing* the refill due date of the first prescription with the date dispensed for a second prescription; and

(i)   for each comparison made in step (h), *categorizing the de-identified patient based on* the duration between the refill due date of the first prescription and the date dispensed for the second prescription.

For example, with respect to claim 25, Portwood and Edelson in combination do not suggest to a person of ordinary skill in the art:

(a)   *a mass storage device for storing a plurality of historical de-identified patient prescription records* corresponding to prescriptions *issued to at least one de-identified patient* by at least one physician, *each record including a de-identified patient identification number*, dosage, number of days supplied and prescription product information, dosage, fill date, and number of days supplied;

(b)   *an input device*, coupled to the mass storage device, *for receiving user-specified information which defines a subset of the plurality of historical de-identified patient* prescription records;

(c)   *a prescription categorizer*, coupled to the input device, *configured to compare* the dosage and the prescription product information contained in *a first historical de-identified patient prescription record* with the dosage and prescription product information contained in *a second historical de-identified patient prescription record*, and to categorize a prescription based on a change in dosage or prescription product; and

(d)   *a persistence calculator*, coupled to the prescription categorizer, configured to determine the due date of a first prescription based on the dosage and the number of days supplied, to compare the due date of the first prescription with the fill date of a second

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prescription, and *to categorize the de-identified patient* based on the duration between the due date of the first prescription and the fill date of the second prescription.

Appellants again submit that Edelson and Portwood do not relate to "de-identified" patient records" or provide any suggestion to a person of ordinary skill in the art for the processing of such records. Therefore, for at least the foregoing reasons, it is respectfully submitted that a prima facie case that the claims of the present invention are obvious has not been established.

VIII.   CLAIMS APPENDIX

1.   The rejections of the following claims 1-35 is appealed.   A method for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest, comprising the steps of:

(a)   receiving a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including de-identified patient identification number, dosage, and prescription product information;

(b)   receiving user-specified information defining a subset of the historical de-identified patient prescription records;

(c)   extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset;

(d)   for each de-identified patient, comparing dosage and prescription product information contained in a first extracted historical de-identified patient record with dosage and prescription product information contained in a second extracted historical de-identified patient record; and

(e)   for each comparison made in step (d), categorizing a prescription based on a change in dosage or prescription product.

2.   The method of claim 1, wherein the step of receiving user-specified information further comprises receiving information concerning an observation period.

3.	The method of claim 1, wherein the step of extracting de-identified patient prescription records further comprises discarding a historical de-identified patient prescription record having an eligibility of shorter duration than the observation period.

4.	The method of claim 1, wherein the step of categorizing prescriptions further comprises categorizing a prescription of a product as a new therapy start when a de-identified patient has had no other prescriptions in a therapeutic area to which the product pertains.

5.	The method of claim 1, wherein the step of categorizing prescriptions further comprises categorizing a prescription as a therapy switch when a de-identified patient has had no other prescriptions of the product, and when the de-identified patient has had a prescription of a second product within a therapeutic area to which the product pertains that was not prescribed on the same day as the prescription.

6.	The method of claim 1, wherein step of categorizing prescriptions further comprises categorizing a prescription as an add-on therapy when the de-identified patient had no other prescriptions for the product but had a prescription for a second product within the therapeutic area to which the product pertains that was prescribed on the same day.

7.	The method of claim 1, wherein the step of categorizing prescriptions further comprises categorizing a prescription as a titration decrease when a de-identified patient has previously had a prescription for the product at a higher dosage.

8.	The method of claim 1, wherein the step of categorizing prescriptions further comprises categorizing a prescription as a titration increase when a de-identified patient has previously had a prescription for the product at a lower dosage.

9.   The method of claim 1, wherein the step of categorizing prescriptions further comprises categorizing a prescription as continued therapy when a de-identified patient has previously had a prescription for the product at the same dosage.

10.   A method for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest comprising the steps of:

(a)   receiving a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including de-identified patient identification number, prescription product information, date dispensed, dosage, number of days supplied, and refill information;

(b)   receiving user-specified information defining a subset of the historical de-identified patient prescription records;

(c)   extracting at least one relevant historical de-identified patient prescription record from the received historical de-identified patient prescription records based on the subset;

(d)   for each de-identified patient, comparing dosage and prescription product information contained in a first extracted historical de-identified patient record with dosage and prescription product information contained in a second extracted historical de-identified patient record;

(e)   for each comparison made in step (d), categorizing a prescription based on a change in dosage or prescription product;

(f)   extracting at least one relevant historical de-identified patient prescription record from the prescriptions categorized at step (e) based on the refill information;

(g) for each de-identified patient, determining a refill due date based on the dosage and the number of days supplied for a first prescription;

(h) for each de-identified patient, comparing the refill due date of the first prescription with the date dispensed for a second prescription; and

(i) for each comparison made in step (h), categorizing the de-identified patient based on the duration between the refill due date of the first prescription and the date dispensed for the second prescription.

11. The method of claim 10, wherein the step of receiving user-specified information further comprises receiving information concerning an observation period.

12. The method of claim 11, further comprising a step of discarding, after step (e), a historical de-identified patient prescription record for a de-identified patient having more than one physician during the observation period.

13. The method of claim 11, wherein the step of extracting de-identified patient prescription records based on refill information further comprises discarding a historical de-identified patient prescription record not having a refill due within the observation period.

14. The method of claim 10, wherein the step of categorizing prescriptions further comprises categorizing a prescription of a product as a new therapy start when a de-identified patient has had no other prescriptions in a therapeutic area to which the product pertains.

15. The method of claim 10, wherein the step of categorizing prescriptions further comprises categorizing a prescription as a therapy switch when a de-identified patient has had no other prescriptions of the product, and when the de-identified patient has had a

prescription of a second product within a therapeutic area to which the product pertains that was not prescribed on the same day as the prescription.

16.   The method of claim 15, further comprising a step of discarding, after step (e), a historical de-identified patient prescription record for a prescription categorized as a therapy switch.

17.   The method of claim 10, wherein the step of categorizing prescriptions further comprises categorizing a prescription as a titration decrease when a de-identified patient has previously had a prescription for the product at a higher dosage.

18.   The method of claim 17, further comprising a step of discarding, after step (e), a historical de-identified patient prescription record for a prescription categorized as a titration decrease.

19.   The method of claim 10, wherein the step of categorizing prescriptions further comprises categorizing a prescription as a titration increase when a de-identified patient has previously had a prescription for the product at a lower dosage.

20.   The method of claim 19, further comprising a step of discarding, after step (e), a historical de-identified patient prescription record for a prescription categorized as a titration increase

21.   The method of claim 10, wherein the step of categorizing the de-identified patient based on the duration between the due date of the first prescription and the fill date of the second prescription further comprises categorizing the de-identified patient as persistent if the duration is shorter than a predetermined number of days.

22.   The method of claim 21, wherein the step of categorizing the de-identified patient based on the duration between the due date of the first prescription and the fill date of the second prescription further comprises categorizing the de-identified patient as non-persistent if the duration is greater than a predetermined number of days.

23.   The method of claim 22, further comprising a step of determining, after step (i), the total number of persistent de-identified patients and the total number of non-persistent de-identified patients for each physician.

24.   The method of claim 23, further comprising a step of calculating, after the step of determining the total number of persistent de-identified patients and the total number of non-persistent de-identified patients for each physician, persistence of the physician by dividing the total number of persistent de-identified patients by the total number of de-identified patients for each physician.

25.   A system for generating a profile concerning prescription therapy practices of at least one physician in a therapeutic area of interest, comprising:

(a)   a mass storage device for storing a plurality of historical de-identified patient prescription records corresponding to prescriptions issued to at least one de-identified patient by at least one physician, each record including a de-identified patient identification number, dosage, number of days supplied and prescription product information, dosage, fill date, and number of days supplied;

(b)   an input device, coupled to the mass storage device, for receiving user-specified information which defines a subset of the plurality of historical de-identified patient prescription records;

(c)   a prescription categorizer, coupled to the input device, configured to compare the dosage and the prescription product information contained in a first historical de-identified patient prescription record with the dosage and prescription product information contained in a second historical de-identified patient prescription record, and to categorize a prescription based on a change in dosage or prescription product; and

(d)   a persistence calculator, coupled to the prescription categorizer, configured to determine the due date of a first prescription based on the dosage and the number of days supplied, to compare the due date of the first prescription with the fill date of a second prescription, and to categorize the de-identified patient based on the duration between the due date of the first prescription and the fill date of the second prescription.

26.   The system of claim 25, wherein the prescription categorizing is configured to categorize a prescription of a product as a new therapy start when a de-identified patient has had no other prescriptions in a therapeutic area to which the product pertains.

27.   The system of claim 25, wherein the prescription categorizing is configured to categorize a prescription of a product as a therapy switch when a de-identified patient has had no other prescriptions of the product, and when the de-identified patient has had a prescription of a second product within a therapeutic area to which the product pertains that was not prescribed on the same day as the prescription.

28.   The system of claim 25, wherein the prescription categorizing is configured to categorize a prescription of a product as an add-on therapy when the de-identified patient had no other prescriptions for the product but had a prescription for a second product within the therapeutic area to which the product pertains that was prescribed on the same day.

29.   The system of claim 25, wherein the prescription categorizing is configured to categorize a prescription of a product as a titration decrease when a de-identified patient has previously had a prescription for the product at a higher dosage.

30.   The system of claim 25, wherein the prescription categorizing is configured to categorize a prescription of a product as a titration increase when a de-identified patient has previously had a prescription for the product at a lower dosage.

31.   The system of claim 25, wherein the prescription categorizing is configured to categorize a prescription of a product as continued therapy when a de-identified patient has previously had a prescription for the product at the same dosage.

32.   The system of claim 25, wherein the persistence calculator is further configured to categorize the de-identified patient as persistent if the duration between the due date of the first prescription and the fill date of the second prescription is shorter than a predetermined number of days.

33.   The system of claim 25, wherein the persistence calculator is further configured to categorize the de-identified patient as non-persistent if the duration between the due date of the first prescription and the fill date of the second prescription is greater than a predetermined number of days.

34.   The system of claim 25, wherein the persistence calculator is further configured to determine the total number of persistent de-identified patients and the total number of non-persistent de-identified patients for each physician.

35.   The system of claim 34, wherein the persistence calculator is further configured to determine the persistence of the physician by dividing the total number of persistent de-identified patients by the total number of de-identified patients for each physician.

IX.   <u>EVIDENCE APPENDIX</u>

None.

X, <u>RELATED PROCEEDINGS APPENDIX</u>

None.

For the foregoing reasons, the Examiner' rejection of claims 1-3 should be reversed.

Dated: June 18 2007

Respectfully submitted,

By: _____

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